

Transforaminal steroid injections for the treatment of cervical radiculopathy: a prospective and randomised study

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Abstract Steroid injections are often employed as an alternative treatment for radicular pain in patients with degenerative spinal disorders. Prospective randomised studies of the lumbar spine reveal contradictory results and non-randomised and most often retrospective studies of the cervical spine indicate pain reduction from steroid injections. No prospective randomised study on transforaminal steroid injections for the treatment of radicular pain in the cervical spine focusing on short-term results has been performed. Forty consecutive patients were employed for the study. The inclusion criteria were one-sided cervical radiculopathy with radicular distribution of arm pain distal to the elbow and corresponding significant degenerative pathology of the cervical spine at one or two levels on the same side as the radicular pain and visualised by MRI. A transforaminal technique was used for all injections. A positive response to a diagnostic selective nerve root block at one or two nerve roots was mandatory for all patients. The patients were randomised for treatment with steroids/local anaesthetics or saline/local anaesthetic. Only the neuroradiologist performing the blocks was aware of the content of the injection; all other persons involved in the study were blinded. Follow up was made 3 weeks

after the randomised treatment by a clinical investigation and with a questionnaire focusing on the subjective effects from the injections. At follow up, there were no differences in treatment results in the two patient groups. Statistical analysis of the results confirmed the lack of difference in treatment effect. Further studies have to be performed before excluding steroids in such treatment and for evaluating the influence of local anaesthetics on radiculopathy in transforaminal injections.

Keywords Nerve root block · Cervical spine · Radiculopathy · Treatment · Randomised

Introduction

Steroid injections are commonly employed as an alternative treatment for radicular pain in patients with degenerative spinal disorders. Prospective randomised studies of the lumbar spine reveal contradictory results on the effectiveness of steroid injections [6, 10, 16, 19, 23, 24, 33, 34, 36]. Non-randomised studies of the cervical spine indicate pain reduction from steroid injections. However, most studies are retrospective [8, 11, 12, 28–31].

To date, no prospective randomised study on transforaminal steroid injections for the treatment of radicular pain in the cervical spine has been performed.

At our hospital, a transforaminal technique is employed for both diagnostic and therapeutic spinal injections. A significant proportion of patients with cervical radiculopathy referred for evaluation/assessment undergo selective diagnostic nerve root

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blocks (SNRB) prior to treatment decision-makings, especially if MRI examination reveals significant pathology at multiple levels or if a negative correlation to clinical findings is demonstrated [1, 2, 15, 17, 18, 27, 32]. Although our experience using transforaminal steroid injections for treatment of cervical radiculopathy was positive in selected patients, a significant number of patients required follow-up treatment or surgical intervention as a consequence of desisting effect.

The aim of the study is to assess the short-term effect of a single dose of corticosteroids injected close to cervical nerve roots in patients with cervical radiculopathy with radicular pain. The diagnosis is based on history, clinical examination, MRI of the cervical spine, and positive response to diagnostic SNRB.

Clinical materials and methods

The present prospective randomised study includes 40 consecutive patients, 20 men and 20 women, presenting with cervical radiculopathy. The mean age was 51 years (range 27–65), with mean symptom duration of 31 months (range 3–120) (Table 1). The inclusion criteria were one-sided cervical radiculopathy with radicular distribution of arm pain distal to the elbow and corresponding significant degenerative pathology of the cervical spine, at one or two levels on the same side as the radicular pain and visualised by MRI. Only MRI pathology with a close relation to the nerve root(s) is classified as significant. A positive response to a diagnostic transforaminal SNRB, at level(s) presenting with MRI pathology on the same side as the radicular pain, was mandatory for all patients. In all 40 patients, the performed investigations indicated affection of cervical nerve roots based on a degenerative disease in the cervical spine. Patients with spinal cord compression and/or myelopathy were excluded. Informed consent was used. The ethics committee at the University Hospital of Lund, Sweden approved the study.

Patient selection

Patients referred to our department with cervical radiculopathy routinely undergo clinical examination by a neurosurgeon, with MRI investigation of the cervical spine. Patients may also undergo investigations with diagnostic transforaminal SNRB with 0.5 ml Carbocain® (Mepivacaine, 10 mg/ml, Astra, Sweden) at levels associated with significant degenerative pathology on

MRI. Consenting patients having undergone these investigations that fulfilled the inclusion criteria were consecutively randomised for treatment with transforaminal injection(s) of the nerve root(s).

MRI evaluation

Prior to randomised treatment, MRI evaluation was assessed as follows: firstly, by a specially trained radiologist at the referring hospital. Secondly, a neuroradiologist at the Department of Neuroradiology at our hospital evaluated and demonstrated the MRI at a clinical conference with the neurosurgeons. Thirdly, the neuroradiologist performing the diagnostic SNRB reviewed the MRI prior to the root block procedure. Before the randomised treatment, the neuroradiologist performing the injections once again evaluated the MRI.

Selection of nerve roots for randomised treatment

Nerve roots on the same side as the radicular pain, at levels presenting with significant degenerative pathology on MRI and responding with a significant pain reduction to diagnostic SNRB, were randomised for treatment. Consequently, patients with positive response to SNRB at one level received the random treatment at one level, and patients with positive response to SNRB at two levels received the random treatment at both levels.

Randomisation

The 40 patients were randomised into two equal treatment groups. One group received treatment with 0.5 ml Carbocain and 1 ml Depo Medrol® (40 mg methylprednisolone acetate) per injection, and the control group received treatment with 0.5 ml Carbocain (Mepivacaine) and 1 ml saline per injection. Only the neuroradiologist performing the blocks was aware of the content of the injections. The patient and the evaluating neurosurgeon/physiotherapist were blinded.

Criteria of positive response to the diagnostic SNRB

If the patient reported a significant subjective arm pain relief (radicular pain) and presented at least 50% arm pain reduction on an visual analogue scale at follow up 30 min after the SNRB, the diagnostic SNRB was classified as positive [2].

Table 1 Patient data, randomised treatment, and treatment results

No.	Sex	Age	Diagnose	Duration of symptom (months)	Roots	Treatment	Treatment effect ^a (at 3 weeks)
1	F	49	FS	72	6	S	0
2	M	56	FS	24	7	S	0
3	F	43	HD	14	5+6	S	0
4	M	57	HD	60	6	S	+
5	F	56	FS	48	6	S	0
6	M	61	FS	13	6+7	S	0
7	F	54	FS	72	6+7	S	0
8	F	45	FS	9	6	S	0
9	M	52	FS	3	6+7	S	0
10	M	45	FS	6	7	S	+
11	M	64	FS	48	5+6	S	+
12	F	43	HD	24	6	S	0
13	F	59	FS	84	6	S	0
14	M	51	FS	60	7	S	+
15	F	27	FS	24	7+8	S	+
16	F	55	HD	22	7	S	+
17	F	43	FS	72	7	S	0
18	F	44	SD	12	7	S	0
19	M	39	FS	12	5+6	S	0
20	M	47	FS	11	6	S	0
21	M	48	FS	24	6	C	+
22	F	55	FS	4	6	C	+
23	F	56	FS	19	6+7	C	0
24	F	41	FS	24	6	C	0
25	M	52	SD	8	8	C	0
26	F	65	HD	32	5	C	0
27	M	51	FS	12	7	C	+
28	M	62	FS	45	6	C	0
29	F	57	HD	24	5	C	0
30	F	56	FS	120	6+7	C	0
31	M	52	HD	48	5	C	0
32	M	50	HD	48	7	C	0
33	F	57	HD	14	6+7	C	0
34	M	40	FS	10	4	C	+
35	M	51	FS	36	6	C	0
36	M	58	HD	12	7	C	0
37	F	63	FS	12	6+7	C	+
38	F	45	HD	24	6	C	+
39	M	47	HD	5	6	C	0
40	M	44	FS	18	6	C	0
Mean		51		31			

C control, *F* female, *FS* foraminal stenosis, *HD* hard disc (spondylosis + soft disc), *M* male, *No.* patient number, *Roots* nerve roots receiving randomised treatment, *SD* soft disc, *S* steroid
^a+—significant subjective reduction of radicular pain and/or neurological deficits, 0—no reduction of radicular pain and/or neurological deficits

Injection technique

Performed by a neuroradiologist using fluoroscopy, the same transforaminal injection technique was used both for diagnostic block as well as for the randomised block [2, 17, 18]. To determine the correct position for injections, thus minimising the risks of intravascular or intradural injection, a small amount of contrast medium was introduced prior to injection [3, 5, 13, 25].

Follow up

Patients were evaluated immediately prior to and 3 weeks following the randomised injections. All evalu-

ations were performed by a neurosurgeon and a physiotherapist, and included patient examination and completion of subjective symptom/reaction questionnaire. In three of the patients, the follow up had to be made by telephone.

Questionnaire

A questionnaire including ten questions was used as follow up of the randomised treatment (Table 2). The aim of the questionnaire was to cover subjective changes in symptoms associated with cervical radiculopathy, including location of pain, muscle strength, sensory changes, analgesic dose, and sleep quality. The

Table 2 Design of follow-up questionnaire used to detect effect from the random treatment

Have You felt any changes in arm pain?	No	Yes, it increased	Yes, it decreased
Have You felt any changes in neck pain?	No	Yes, it increased	Yes, it decreased
Have You felt any changes in shoulder pain?	No	Yes, it increased	Yes, it decreased
Have You felt any changes in your headache?	No	Yes, it increased	Yes, it decreased
Has the power of Your hand/arm undergone any changes?	No	Yes, it increased	Yes, it decreased
Has the sensibility in Your hand/arm undergone any changes?	No	Yes, it increased	Yes, it decreased
Has Your neck mobility undergone any changes?	No	Yes, to the better	Yes, to the worse
Have Your arm mobility undergone any changes?	No	Yes, to the better	Yes, to the worse
Have You changed your intake of analgesics?	No	Yes, it increased	Yes, it decreased
Have Your quality of sleep undergone any changes?	No	Yes, to the better	Yes, to the worse

patients were encouraged to report any additional effect, if present. Following the completion of the questionnaire, a clinical investigation was undertaken.

In order to assess early as well as late changes from the randomised treatment, the patients were asked to relate changes of symptoms to the first, second, and third weeks.

Data analysis

The clinical criteria of positive response to the randomised treatment were a significant subjective reduction of the radicular pain and/or significant subjective reduction of neurological symptoms. When performing the statistical analysis of treatment result, all data from the questionnaire were compared (Table 3).

Questionnaire results were compiled according to first, second, and third weeks following treatment. All data were analysed using a computer software package (SPSS, release 11.0.0; SPSS, Chicago, IL, USA).

Results

Patients randomised for steroid treatment

Thirteen patients received treatment with steroids and local anaesthesia at one level and seven patients at two levels. Eight of the 20 patients reported a positive response from the treatment, and in seven of the eight patients, the effect lasted 7 days or more. Six patients reported a remaining effect from the treatment at follow up after 3 weeks (Table 1).

Patients randomised for control treatment

Sixteen patients received treatment with local anaesthesia and saline at one level and four patients at two levels. Seven of the 20 patients reported a positive response from the treatment, and in six patients, the

effect lasted 7 days or more. Six patients reported a remaining effect from the treatment at follow up after 3 weeks (Table 1).

Comparison of amount of events with subjective symptom reduction

For all 40 patients in the study, a total of 400 questions relating to changes in symptoms were answered. In the steroid group, 34 (17%) of the answers indicated reduction in symptoms while in the saline group, 32 (16%) of the answers indicated reductions in symptoms (Table 3).

Statistical analysis

Statistical analysis revealed no significant difference ($P < 0.05$) for any of the measured parameters when comparing the results between the two treatment groups at 1, 2, or 3 weeks after the randomised treatment (Table 4).

Complications

No serious complication resulted from the study. One patient experienced an allergic skin reaction. Four patients reported an increase in radicular pain for a few days after the injections. At 3 weeks follow up, none of the patients reported persisting negative effect from the treatment.

Discussion

General discussion

The results in this study showed no short-term difference between the combination of steroid and local anaesthetics, and the combination of saline and local anaesthetics for the treatment of radiculopathy based

Table 3 Effect from the random treatment for all patients at follow up after 3 weeks

No.	A	N	S	H	Ph	Sha	Mn	Ma	D	Sl
1	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0
3	0	+	+	+	0	0	+	0	0	0
4	+	0	0	0	+	0	0	+	+	+
5	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0
10	+	+	0	0	0	+	+	+	0	+
11	0	0	+	0	0	0	+	0	0	0
12	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0
14	+	+	+	+	0	0	+	0	+	+
15	+	+	+	+	0	0	0	0	+	+
16	+	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0
20	+	0	+	0	0	0	0	+	0	0
21	0	0	0	0	+	+	0	+	0	0
22	+	+	+	0	+	+	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0
27	+	+	+	0	0	0	+	0	0	+
28	+	0	0	0	0	0	+	0	0	0
29	0	0	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0	0	0
31	0	0	0	0	0	0	0	0	0	0
32	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0
34	+	+	+	0	+	+	+	+	0	0
35	+	+	+	+	0	0	+	+	+	+
36	0	0	0	0	0	0	0	0	0	0
37	+	0	0	0	0	0	0	0	+	0
38	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0

Patient numbers 1–20 received steroid/local anaesthetics and patient numbers 21–40 received saline/local anaesthetics for treatment

No. patient number, A arm pain, N neck pain, S shoulder pain, H headache, Ph power arm/hand, Sha sensory arm/hand, Mn movement neck, Ma movement arm, D analgesics, Sl sleep

+—positive effect, 0—no effect

on degenerative disease in the cervical spine. This is of interest as steroid injections are used as a non-surgical approach to cervical radiculopathy with radicular pain [8, 11, 12, 28–31].

Our rigorous diagnostic methods contradict errors in selecting patients with cervical radiculopathy with radicular pain. All the patients in the present study presented with radicular pain and significant imaging pathology as well as a positive response to a diagnostic SNRB at the nerve roots receiving treatment. And, as predictors of good outcome when using cervical epidural steroid injections are radicular pain and a corresponding imaging diagnosis of spondylosis and hard discs, the patients in the present study should be optimal for transforaminal steroid injections [12]. It was difficult to keep the neuroradiologist performing the

block blinded as the steroid solution is white in colour and the control injection with saline and local anaesthetics is a clear solution. For safety reasons, the syringe must be under visual control during the injection. We used the combination of steroids and local anaesthesia to minimise the sometime painful local effect from the steroids, which might have revealed the content in the injections for the patients. Consequently, we also used local anaesthesia in the control group. The combination of steroids and local anaesthesia is often used in clinical practise when performing spinal therapeutic injections, both epidural and transforaminal. To avoid any kind of misunderstanding at follow up, we very carefully correlated the clinical findings to the answers in the questionnaire from the patient. To make the follow-up procedure simple and

Table 4 Statistical analysis of results from the questionnaire when comparing the two treatment groups at the first, second, and third weeks after the randomised treatment

<i>P</i> -value for Pearson chi-square test			
Parameter	One week	Two weeks	Three weeks
Arm-pain	0.464	0.465	0.705
Neck-pain	0.705	0.677	1.000
Shoulder pain	1.000	0.429	1.000
Headache	0.292	0.072	0.147
Power	0.147	0.072	0.072
Sensory	0.292	0.376	0.376
Neck-movement	0.705	0.331	1.000
Arm movement	0.633	1.000	1.000
Medication	0.633	0.292	0.548
Sleep	0.376	0.151	0.292

straightforward, we focused only on the most important issue, the patient's subjective response to the treatment, and related it to the clinical investigation. Although a high number of studies investigating the use of steroids for treatment of radicular pain have been performed, mostly in the lumbar and to a lesser degree in the cervical spine, few of them are randomised and the results are not unambiguous.

The proposed reduction of inflammation from steroids seems to be a reasonable effect as inflammation might be involved in the pain produced by cervical radiculopathy [9, 14, 20]. However, the results in this study raise some doubts. Other randomised studies evaluating the use of steroid injections in treatment of disorders where steroid injections are often used (shoulder, carpal tunnel, facet joints, lumbar discs) have also reported lack of effect from the steroid injections, especially in the long term [4, 7, 21, 26].

Effect from local anaesthesia

Reduced inflammation on nucleus pulposus-induced nerve root injury as well as leukocyte inhibitory activity has been reported from lidocaine [35]. Theoretically, there could be a longstanding symptom reduction from local anaesthesia on radiculopathy due to an anti-inflammatory effect and thus explain the results in the control group in the present study. Previously, we have seen patients presenting with longstanding pain relief from a diagnostic nerve root block. All 40 patients in the present study had prior to treatment undergone investigations with diagnostic SNRB using the same amount of local anaesthetics as in the study and none reported persisting pain relief after the diagnostic SNRB. Could it be an effect from

repetitive injections of local anaesthetics as every patient in this study had two injections containing the drug or is it a placebo effect in the control group?

Experience from other studies with cervical steroid injections

In a retrospective study, Slipman et al. achieved 60% good/excellent results in 20 patients with non-traumatic cervical radiculopathy treated with transforaminal injections using a combination of steroids and local anaesthesia with an average of 2.2 injections per patient [28]. In another retrospective study using transforaminal steroid injections, the same author reported good/excellent outcome in 3 (20%) out of 15 patients with traumatic cervical spondylotic radiculopathy after an average of 3.7 injections [30].

In a prospective study, Bush and Hillier reported 68 patients with cervical radiculopathy treated with a mixture of three different injection techniques including transforaminal and epidural injections [8]. They combined steroids with local anaesthesia and performed 2.5 injections (range 1–6) per patient with 76% of the patients free from arm pain at follow up after an average of 39 months (4–112).

In a recent prospective study including 30 patients treated by CT guided cervical foraminal injections, 37% had excellent results [31]. In a study with randomised steroid injections for the treatment of neck pain from zygapophyseal joints, the authors reported lack of effect from steroids [4]. Our own overall impression from using transforaminal steroid injections in patients with cervical radiculopathy is that a good effect can be achieved on radicular pain in selected patients.

Future

Initially, we considered relating the results in the present study to placebo but with our own experience in our minds, we imagine the problem to be more complex. De facto, 30% of the patients in both treatment groups had a substantial effect. Maybe subgroups of patients may benefit from the treatment and, if so, is it possible to reveal any such subgroup?

For this reason, we propose that future studies evaluating steroid effect on radiculopathy in the cervical spine should separate “hard discs,” soft discs, and foraminal stenosis from each other and treat them as three different diagnostic entities as the pathophysiology might involve different levels of inflammation and mechanical compression of different structures (lateral part of spinal cord, root entry zone, dorsal root ganglia, ventral root).

However, spondylotic radicular pain decreases over time when treated conservatively and steroid injections can probably help some patients to continue the non-surgical treatment [22]. If it is possible to avoid surgery with transforaminal steroid injections in 30% or more of the patients with cervical radiculopathy with radicular pain that normally undergoes surgery, it might be a good reason to continue the treatment.

Conclusion

Using a single transforaminal injection for the treatment of cervical radiculopathy presenting with radicular pain, the combination of steroids and local anaesthetics did not provide more symptom reduction than the combination of saline and local anaesthetics. Further studies have to be performed before excluding steroids in such treatment and for evaluating the influence of local anaesthetics on radiculopathy in transforaminal injections.

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